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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/623,371

07/18/2003

Karen L. Fearon

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07/28/2006

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EXAMINER

MINNIFIELD, NITA M

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 07/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/623,371	<b>Applicant(s)</b> FEARON ET AL.	
	<b>Examiner</b> N. M. Minnifield	<b>Art Unit</b> 1645	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 May 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 2, 5-10, 14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4 and 11-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/8/03</u> <u>19 pp.</u> | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

1. Applicant's election without traverse of Group I, nucleic acid species 5'-TCGTCGA, and non-nucleic acid spacer moiety HEG (specifically claims 1, 3, 4 and 11-13) in the reply filed on May 3, 2006 is acknowledged. Claims 1, 3, 4 and 11-13 have been examined.

2. Claims 2, 5-10, 14 and 15 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 3, 2006.

3. The Examiner notes Applicants' request for rejoinder of withdrawn method claims 14 and 15 upon allowance of the product claims from which they depend, in accordance with MPEP 821.04.

4. The use of trademarks has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 1, 3, 4 and 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and indefinite in the recitation of the abbreviations (HEG, TEG, IFN- $\alpha$ ) in the claims. Full terminology should be used in the first instance in the claims without the additional use of redundant abbreviations in parentheses or otherwise. Correction is required. Claim 4 is vague and indefinite in the recitation of "CIC"; the claim does not define what the "CIC" comprises.

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a

nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1, 3, 4 and 11-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15, and 20-23 of copending Application No. 10/176883. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of both applications are drawn to chimeric immunomodulatory compounds comprising nucleic acid moieties and non-nucleic acid spacer moieties as well as pharmaceutically acceptable excipients, antigens and cationic microspheres.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 1, 3, 4 and 11-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 22-25 of copending Application No. 10/177826. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of both applications are drawn to chimeric immunomodulatory compounds comprising nucleic acid moieties and non-nucleic acid spacer moieties

as well as pharmaceutically acceptable excipients, antigens and cationic microspheres.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 1, 3, 4, and 11-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5 and 6 of copending Application No. 10/328578. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of both applications are drawn to chimeric immunomodulatory compounds comprising nucleic acid moieties and non-nucleic acid spacer moieties as well as pharmaceutically acceptable excipients, antigens and cationic microspheres.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Schwartz et al (WO 98/55495).

The claim is directed to a chimeric immunomodulatory compound (CIC) that stimulates production of IFN- $\alpha$  from human peripheral blood mononuclear cells, said CIC comprising at least three nucleic acid moieties, at least one of which comprises a sequence 5'-TCGY, where Y is selected from the group consisting of XCGX, XTCG, XXCG, and CGXX, where X is any nucleotide, and at least one nonnucleic acid spacer moiety.

Schwartz et al discloses immunomodulatory compositions comprising oligonucleotides that contain at least one immunostimulatory octanucleotide and that the oligonucleotide can be covalently linked/conjugated to an antigen or polysaccharide (i.e. non-nucleic acid spacer moiety) (p. 4; p. 12-13). Schwartz et al discloses that the oligonucleotide contains at least one immunostimulatory oligonucleotide and can also contain multiple immunostimulatory oligonucleotides (p. 10). Schwartz et al discloses a nucleic acid moiety comprising the sequence 5'-TCGY, where Y is AACG (see SEQID NO: 4 and 5, Table 1; Sequence Listing, 35; and claims).

The prior art is silent with regard to stimulating production of IFN- $\alpha$  from human peripheral blood mononuclear cells; however, the compound meets the structural requirements of the claim (i.e. CIC comprising at least three nucleic acid moieties, at least one of which comprises a sequence 5'-TCGY, where Y is selected from the group consisting of XCGX, XTCG, XXCG, and CGXX, where X is any nucleotide, and at least one nonnucleic acid spacer moiety). Since the Patent Office does not have the facilities for examining and comparing applicants' compound with the compound of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed compound and the compound of the prior art. See In

re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

13. No claims are allowed.

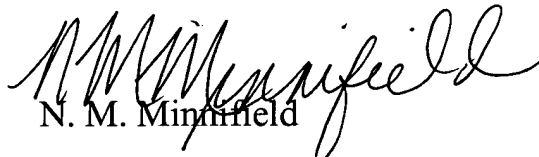
14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
N. M. Minnifield  
Primary Examiner  
Art Unit 1645

NMM

July 21, 2006